

Application No. 10/679,916
Docket No. IB-10 (A4-1766)
Amendment dated August 4, 2006
Reply to Office Action of May 4, 2006

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Amendments to the Specification:

Please replace the sole paragraph under the section "Summary of the Invention" with the following amended paragraph:

The invention comprises a telemetric sensing system for noninvasively monitoring pressure and/or pressure gradients in a cardiac conduit. The system includes one or more implantable sensor unit(s) and a companion reader unit. The ~~batteryless, wireless pressure~~ sensor unit, which is preferably batteryless and wireless, is chronically located within the conduit, or around in a close proximity. For valveless conduits, a sensor unit is placed at either end of the conduit, or around it. For valved conduits, one or more sensor units ~~sensors~~ are located both proximal and distal to the valve, allowing the pressure gradient across the valve to be monitored. One sensor unit can indicate occlusion; however, two sensor units ~~sensors~~ will allow the occlusion to be located (e.g. proximal/middle/distal along the conduit). As well, with two sensor units, ~~sensors~~, flow rates may be deduced or estimated. Furthermore, trend analysis of the pressures and/or flow rate within the conduit can allow a time-to-failure estimate.

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Please replace the paragraph bridging pages 3 and 4 with the following amended paragraph:

In order to provide for the effective monitoring, management, and tailoring of treatment for patients with heart defects, the present invention provides a cardiac conduit with a wireless sensing system. The system comprises an external readout unit as well as at least one implantable sensor 50 ~~one or more implantable pressure monitor 50~~ which is securely anchored in a conduit 60, as shown in Fig. 1 or in the vicinity of the conduit. The readout unit both transmits power to and receives transmitted data from the sensor 50 ~~implant~~. Data transmitted from the sensor 50 ~~implantable device~~ may include pressure, calibration data, identification data, fluid flow rate, and/or other physiologic parameters. The readout unit may include a barometric pressure sensor in order to compensate for variation in atmospheric pressure.

Please replace the first full paragraph on page 4 with the following amended paragraph:

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As noted above, at least one sensor 50 ~~The batteryless,~~
~~wireless pressure sensor unit(s)~~ is chronically located within the
conduit 60, or around it. For valveless conduits 60, one or more
sensors 50 are placed at either end of the conduit 60. For valved
conduits 60, a sensor 50 is located both proximal and distal to the
valve, allowing the pressure gradient across the valve to be
monitored. One sensor 50 can indicate occlusion; however, two
sensors 50 will allow the occlusion to be located (e.g.
proximal/middle/distal along the conduit 60). As well, with two sensors
50, flow rates may be deduced or estimated. Furthermore, trend
analysis of the pressures and/or flow rate within the conduit 60 can
allow a time-to-failure estimate.

Please replace the second full paragraph on page 4 with the following amended
paragraph:

The ~~batteryless,~~ wireless telemetry link between the sensor(s)
50 and the reader unit is preferably implemented using either a
resonant or passive, magnetically coupled scheme. A resonant
device 101 (shown in Figure 2) is the simplest approach, and consists

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only of a packaged inductor coil 103 and capacitive pressure sensor 102. Together, the sensor 102 and coil 103 ~~two elements~~ form a circuit that has a specific resonant frequency. At that resonant frequency, the circuit presents a measurable change in magnetically coupled impedance load to an external coil 105 associated with an external reader 104. Because the resonant frequency is a function of the ~~coil~~ inductance of the coil 103 and the ~~sensor~~ capacitance of the sensor 102, as pressure changes the resonant frequency changes as well. The external ~~An external~~ reader 104 is able to determine pressure by monitoring the frequency at which the coil antenna 105 impedance changes.

Please replace the paragraph bridging pages 4 and 5 with the following amended paragraph:

The preferred communication scheme for the present invention, shown in Fig. 3 as being between a passive implant device 201 and an external reader 202, is based on magnetic telemetry. Devices that have on-board circuitry but still receive their operating power from an external source (i.e., are batteryless) are referred to herein as

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passive. Without the external reader 202 ~~passive devices 201~~
(~~shown in Figure 3~~). ~~Without an external reader~~ present, the implant device 201 lays passive and without any internal means to power itself. When a pressure reading is desired, the reader ~~device~~ 202 is brought into a suitable range to the implant device 201. In this case the external reader 202 uses an alternating magnetic field to induce a voltage in the implant device 201. When sufficient voltage has been induced in the implant device 201, a rectification circuit 203 converts the alternating voltage on the receiver coil 204 into a direct voltage that can be used by the electronics 205 as a power supply for signal conversion and communication. At this point the implant device 201 can be considered alert and, in the preferred embodiment, also ready for commands from the reader 202. The maximum achievable distance is mostly limited by the magnetic field strength necessary to turn the implant device 201 on. This telemetry scheme has been proven and used extensively in the identification and tracking industry (e.g., implantable RF ID technology from Texas Instruments or Digital Angel) with a great deal of acceptance and success.

Please replace the first full paragraph on page 5 with the following amended

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paragraph:

Once the direct voltage in the implant device 201 has been established for the circuit operation, a number of techniques may be used to convert the ~~sensor~~ output of the device 201 into a form suitable for transmission back to the reader 202. ~~device~~. In the preferred embodiment, a capacitive pressure sensor 206 and sigma delta conversion or capacitance to frequency conversion of the sensor output may be easily used. Capacitive sensors are preferred due to the small power requirements for electronics when reading capacitance values. Many pressure sensors are based on piezoresistive effects and, while suitable for some applications, do suffer in this application due to the higher power levels needed for readout. Sigma delta converters are preferred due to the tolerance of noisy supply voltages and manufacturing variations.

Please replace the first full paragraph on page 6 with the following amended paragraph:

In addition to the many available modulation techniques, there

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are many technologies developed that allow the implant device 201 to communicate back to the reader 202 the signal containing pressure information. It is understood that the reader 202 ~~device~~ may transmit either a continuous level of RF power to supply the ~~implant's~~ needed energy for the device 201, or it may pulse the power allowing temporary storage in a battery or capacitor device (not shown) within the device 201. Similarly, the implant device 201 of Fig. 3 may signal back to the reader 202 at any interval in time, delayed or instantaneous, during reader RF (Radio Frequency) transmission or alternately in the absence of reader transmission. The implant device 201 may include a single coil antenna 204 for both reception and transmission, or it may include two antennas 204 and 221, one each for transmission ~~204~~ and reception, respectively. ~~221~~. There are many techniques for construction of the reader coil 219 and processing electronics known to those skilled in the art. The reader 202 may interface to a display, computer, or other data logging devices 220.

Please replace the second full paragraph on page 6 with the following amended paragraph:

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The electronic circuit may consist of the coil antenna 204, ~~a receiving inductor coil 204~~, rectification circuitry 203, signal conditioning circuitry 211, and signal transmission circuitry 212.

Please replace the last full paragraph on page 6 with the following amended paragraph:

A large number of possible geometries and structures are available for the coil 204 and ~~are receiver coil and~~ known to those skilled in the art. The coil conductor may be wound around a ferrite core to enhance magnetic properties, deposited on a flat rigid or flexible substrate, and formed into a long/skinny or short/wide cylindrical solenoid. The conductor is preferably made at least in part with a metal of high conductivity such as copper, silver, or gold. The coil 204 ~~coil~~ may alternately be fabricated on implantable sensor substrates. Methods of fabrication of coils on the sensor substrate include but are not limited to one or more or any combination of the following techniques: sputtering, electroplating, lift-off, screen printing, and/or other suitable methods known to those skilled in the art.

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Please replace the third full paragraph on page 7 with the following amended paragraph:

The signal transmission circuitry 212 transmits the encoded signal from the signal conditioning circuitry 211 ~~circuitry~~ for reception by the external reader 202. ~~an external reader.~~ Magnetic telemetry is again used for this communication, as the transmission circuitry 212 generates an alternating electromagnetic field that propagates to the reader 202. Either the same coil 204 is used for signal reception and for transmission, or alternately the second coil 221 ~~a second coil 221~~ is dedicated for transmission only.

Please insert the following new paragraph before the last paragraph on page 10:

Finally, the cardiac conduit 60 with the attached sensor 50 and remote readout device can be implemented as part of a closed-loop medical treatment system. Furthermore, if the conduit 60 includes a valve, the cardiac conduit can be incorporated into a closed-loop or open-loop system for control of the valve.

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Please replace the paragraphs under "Abstract" on page 22 of the specification with the following:

A system for non-invasively monitoring one or more physiological parameters such as pressure and/or pressure gradients in a cardiac conduit adapted for blood bypass flow. The system includes the conduit, at least one sensing device chronically located within the conduit, and a non-implantable readout device. The sensing device includes at least one inductor coil and at least one sensor for monitoring the one or more physiological parameters for diagnosis of the condition of the conduit after the conduit is implanted in a patient. The readout device includes at least one inductor coil allowing electromagnetic telecommunication and electromagnetic wireless powering of the sensing device through the inductor coil thereof. ~~—conduit is provided. This system includes one or more implantable sensing devices, and a non-implantable readout device. The implantable sensing device has an inductor and capacitor with an option of having electronic components, as well as a mechanism for anchoring the device inside the patients' body. The external readout device allows electromagnetic telecommunication and wireless~~

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~~powering of the implanted sensor. Data transmitted from the implantable device may include pressure, temperature, calibration data, identification data, fluid flow rate, chemical concentration, and/or other physiologic parameters.~~

~~—————The batteryless, wireless pressure sensor unit(s) is chronically located within the conduit. For valveless conduits, one or more sensors are placed at either end of the conduit. For valved conduits, a sensor is located both proximal and distal to the valve, allowing the pressure gradient across the valve to be monitored. One sensor can indicate occlusion; however, two sensors will allow the occlusion to be located (e.g. proximal/middle/distal along the conduit). As well, with two sensors, flow rates may be deduced or estimated. Furthermore, trend analysis of the pressures and/or flow rate within the conduit can allow a time-to-failure estimate.~~